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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,608	01/18/2002	Tetsumasa Ito	027929.101-US00	4635

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/050,608	Applicant(s) ITO, TETSUMASA	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6/0 9/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-12 in papers filed 19 February 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-12 are indefinite in Claim 1 for the recitation "another location different from the surface of the probe-immobilizing support" because both "location" and "surface" lack proper antecedent basis in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis e.g. replace "another" and "the" with "a".

b. Claim 2 is indefinite in line 3 for the recitation "the surface" because the recitation lacks proper antecedent basis in Claim 1. It is suggested that Claim 2 be amended to provide proper antecedent basis e.g. replace "the" with "a".

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c. Claim 3 is indefinite in line 2 and line 3 for the recitations “the thermal capacity” because the recitation lacks proper antecedent basis in Claims 1 or 2. It is suggested that Claim 3 be amended to provide proper antecedent basis e.g. replace “the” with “a”.

d. Claim 4 is indefinite in line 4 for the recitation “the actuation” because the recitation lacks proper antecedent basis in Claim 1, 2 or 3. It is suggested that Claim 4 be amended to provide proper antecedent basis e.g. replace “the” with “a”.

e. Claim 5 is indefinite for the recitation “consists of a Peltier element or heater” because it is unclear whether “Peltier” modifies the “element” or modifies both the “element” and the “heater”. It is suggested that Claim 5 be amended to clarify.

f. Claim 6 is indefinite for the recitations “the thermal flux” and “the solution containing the target gene” because both “thermal flux” and “solution” lack proper antecedent basis in Claim 1. It is suggested that Claim 6 be amended to provide proper antecedent basis e.g. replace “the” with “a”.

g. Claim 8 is indefinite for the recitations “the circumferential surface”, “the thermal flux” and “the electrode end face” because the recitations lack proper antecedent basis in Claims 1 and 7. It is suggested that Claim 8 be amended to provide proper antecedent basis e.g. replace “the” with “a”.

h. Claim 9 is indefinite in lines 2-3 for the recitation “on the surface thereof” because “surface” lacks proper antecedent basis in Claim 7. It is suggested that Claim 9 be amended to provide proper antecedent basis e.g. replace “the” with “a”.

i. Claim 11 is indefinite in line 9 for the recitation “the temperature” because the recitation lacks proper antecedent basis in Claim 7. It is suggested that Claim 11 be amended to provide proper antecedent basis e.g. replace “the” with “a” or replace “temperature” with “heating and cooling”.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-7, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 1, Lipshutz et al disclose a gene detection system comprising a probe-immobilizing support on which a probe is immobilized (Column 2, lines 16-34 and Column 13, line 25-Column 14, line 11) and heating and cooling means disposed in contact with a location different from a surface of the probe-immobilizing support on which the probe is immobilized (Column 24, line 42-Column 25, line 41 and Fig. 2B #128).

Regarding Claim 2, Lipshutz et al disclose the system wherein the heating and cooling means comprises a soaking component (filter plug membrane incorporating evaporation barrier) disposed in contact with a surface opposite the probe-immobilizing support and a heating and cooling element disposed in contact with the soaking component (Column 17, lines 28-49 and Fig. 2 B #120). Lipshutz et al further teach the embodiment wherein the soaking component comprises a polycarbonate planar piece to which the Peltier element is attached (Example 3, Column 32, line 65-Column 33, line 7).

Regarding Claim 5, Lipshutz et al disclose the system wherein the heating and cooling element consists of a Peltier element (Column 25, lines 36-41 and Example 3, Column 32, line 65-Column 33, line 7).

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Regarding Claim 6, Lipshutz et al disclose the system (Fig. 2B) wherein solution containing the target (i.e. reaction chamber #104) is between the heating and cooling means (#128) and the probe-immobilizing support (i.e. first planar member #106). While they do not specifically teach the device is constructed so that a thermal flux is propagated between the heating and cooling means and the solution, the recitation is functional language which does not describe structural limitations of the device. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). Lipshutz et al teach the device comprising heating and cooling means adjacent to the support (Column 13, line 25-Column 14, line 11).

Regarding Claim 7, Lipshutz et al disclose the system wherein the probe immobilizing support comprises an electrode on which the probe is immobilized and an electrode substrate (Column 26, lines 24-33).

Regarding Claim 10, Lipshutz et al disclose the system wherein the electrodes comprises a plurality of electrodes i.e. electrodes patterned on the surface of the array (Column 26, lines 24-33).

Regarding Claim 12, Lipshutz et al disclose a gene detection device comprising the gene detection system of Claim 1 and control means for controlling heating and cooling means (Column 13, line 25-Column 14, line 11 and Column 25, lines 23-41).

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6. Claims 1- 7 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000).

Regarding Claim 1, Yasuda et al disclose a gene detection system comprising a probe-immobilizing support on which a probe is immobilized (Fig. 2, #14 and Fig. 10-11, #221) and heating and cooling means (Fig. 2, #31; Fig. 10-11, #225) disposed in contact with a location different from a surface of the probe-immobilizing support on which the probe is immobilized (Column 4, lines 54-67 and Column 10, line 56-Column 12, line 12).

Regarding Claim 2, Yasuda et al disclose the system wherein the heating and cooling means comprises a soaking component (i.e. thermally conductive insulating substrate #132) in contact with a surface opposite the probe-immobilizing support and a heating and cooling element disposed in contact with the soaking component (Column 11, lines 43-62 and Fig. 11).

Regarding Claim 3, Yasuda et al disclose the system where the thermal capacity of the soaking component is greater than the thermal capacity of the probe-immobilizing support i.e. the substrate #132 is an insulating substrate (Column 11, lines 43-62).

Regarding Claim 4, Yasuda et al disclose the system wherein the soaking component comprises a temperature sensor (i.e. thermosister, Fig. 11, #231 and temperature control unit, Fig. 11, #133) for measuring temperature and controls the actuation of the heating and cooling element (Column 11, lines 43-62).

Regarding Claim 5, Yasuda et al disclose the system wherein the heating and cooling element consists of a Peltier element (Column 19, lines 5-24).

Regarding Claim 6, Yasuda et al disclose the system wherein the heating and cooling means is provided by convergent light such that thermal flux is propagated between the heating and cooling means and the solution to the probe-immobilizing support (Column 6, line 63-Column 7, line 46 and Fig. 3). While they do not specifically teach the device is constructed so that a thermal flux is propagated between the heating and cooling means and the solution, the recitation is functional language which does not describe structural limitations of the

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device. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). Yasuda et al teach the device comprising heating and cooling means adjacent to the support (Fig. 1, 3 and 11).

Regarding Claim 7, Yasuda et al disclose the system wherein the probe immobilizing support comprises an electrode on which the probe is immobilized and an electrode substrate i.e. the substrate comprises a planer electrode (Column 6, lines 33-42, Fig. 1, not illustrated). Yasuda teach the further embodiment wherein the probes are immobilized on the electrode-containing substrate (Column 11, lines 50-58, Fig. 11, #226).

Regarding Claim 10, Yasuda et al disclose the system wherein the electrodes comprises a plurality of electrodes (Column 11, lines 43-62).

Regarding Claim 11, Yasuda et al disclose the system wherein the electrode substrate comprises a plurality of electrodes substrates supporting the plurality of electrodes and the heating and cooling means independently controls the temperature of each of the plurality of electrode substrates (Column 11, lines 7-23)

Regarding Claim 12, Yasuda et al disclose a gene detection device comprising the gene detection system of Claim 1 and control means for controlling heating and cooling means (Column 10, line 56-Column 12, line 62 and Fig. 10-11).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000) in view of Heller et al (U.S. Patent No. 5,605,662, issued 25 February 1997).

Regarding Claims 8-9, Yasuda et al teach a gene detection system comprising a probe-immobilizing support on which a probe is immobilized (Fig. 2, #14 and Fig. 10-11, #221) and heating and cooling means (Fig. 2, #31; Fig. 10-11, #225) disposed in contact with a location different from a surface of the probe-immobilizing support on which the probe is immobilized (Column 4, lines 54-67 and Column 10, line 56-Column 12, line 12) wherein the probe immobilizing support comprises an electrode on which the probe is immobilized and an electrode substrate i.e. the substrate comprises a planer electrode (Column 6, lines 33-42, Fig. 1, not illustrated) and the further embodiment wherein the probes are immobilized on the electrode-containing substrate (Column 11, lines 50-58, Fig. 11, #226) wherein the surface of the electrode is covered with a heat insulating member (Fig. 11) but they do not specifically teach the system is constructed so that thermal flux from the heating and cooling flows past the electrode face into the solution containing the gene and they are silent regarding the composition of the substrate and electrode. However, Heller et al teach a similar system comprising a probe immobilizing support and heating and cooling means (i.e. electrodes) wherein thermal flux flows past the electrode into the solution containing the gene (Fig 6)

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wherein the electrode comprises gold, silver or copper (Column 12, lines 55-61) and the electrode substrate comprises a ceramic material (Column 14, lines 26-41). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the system of Yasuda et al with the substrate and electrode composition of Heller et al based on their preferred used in the substrate of Heller et al. It would have been further obvious to one of ordinary skill in the art to arrange the system such that thermal flux flows past the electrode end into the solution to thereby provide optimal conditions for gene detection as described by Heller et al (Column 5, lines 24-60).


Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 17, 2003